REMARKS

The Office Action of April 18, 2006 has been carefully reviewed and this paper is Applicants' response thereto. Claims 80, 82-86 and 89-107 are pending. Claims 1-79 and 110-135 are withdrawn. Claims 80, 85, 92, 95-98, 102,103 and 105 were amended. Claims 81, 87-88 and 108-109 are cancelled. The Office Action objected to the drawings as failing to show all the features recited in the claim 85. The Office Action rejected claims 80-86, 89-102 and 104-105 under 35 U.S.C. § 112, ¶ 1 as failing to comply with the written description requirement. Claim 96 was rejected under 35 U.S.C. § 112, ¶ 2 as being indefinite. The Office Action also objected to the specification as failing to provide proper antecedent basis for the claimed subject matter with regards to claims 95-98. The Office Action rejected claims 80-83, 85, 86, 89, 103 and 107 under 35 U.S.C § 102(e) as being anticipated by U.S. Publication No. 2003/0069541 to Gillis *et al.* ("Gillis"). The Office Action rejected claims 80-83, 85, 86, 89, 90, 103, 106 and 107 under 35 U.S.C. § 103(a) as being unpatentable over U.S Patent No. 6,129,685 to Howard, III ("Howard") in view of U.S. Patent No 6,425,887 to McGuckin *et al.* (McGuckin). The Office Action rejected claims 84 and 102 under 35 U.S.C. § 103(a) as being unpatentable over Howard in view of McGuckin in further view of U.S. Patent No. 5,711,316 to Elsberry *et al.* ("Elsberry"). The Office Action rejected claims 91-92, 95-101 and 104-105 under 35 U.S.C. § 103(a) as being unpatentable over Howard in view of McGuckin in further view of U.S. Patent No. 4,533,346 to Cosgrove, Jr., *et al.* (Cosgrove). Claim 94 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Howard in view of McGuckin and Cosgrove and in further view of U.S. Patent Re. No. 36,386 to Abbott *et al.* (Abbott). Claims 80-83, 85-86, 89, 103 and 107 were rejected on the grounds of nonstatutory obviousness-type double patenting in view of U.S. Patent No. 6,353,762 in view of Gillis or U.S. Patent No. 5,964,796 to Imran (Imran).

In response, Applicants respectfully request reconsideration of the application in view of the above amendments and the following remarks.

Objection to the Drawings

The drawings are objected to for failing to disclose every element of claim 85. In response, claim 85 has been amended to recite "The agent delivery system of claim 80, wherein

the therapy delivery device is coupled to a first and a second catheter, wherein the delivery system is configured to deliver at least two drugs through the first and second catheters." If the objection to the drawing is that the figures do not show two catheter ports each coupled to a separate catheter, Applicants respectfully submit such a rejection does not find support in 37 CFR 1.83. 37 C.F.R 1.83(a) merely requires that every feature of the invention be shown. Plainly the figures show a catheter port coupled to a catheter. Nor are Applicants suggesting that the connection of a catheter to a catheter port is new. See Duggan generally and specifically Figures 1, 3 and 9 of Duggan for an example of such a connection. Therefore, given the known nature of connecting a catheter to a catheter port, the suggestion that two ports need to be shown connected to two separate catheters does not seem supported. In particular, 37 CFR 1.83(b) explains that "When the invention consists of an improvement on an old machine the drawings must when possible exhibit, in one or more views, the improved portion itself, disconnected from the old structure, and also in another view, so much only of the old structure as will suffice to show the connection of the invention therewith." Plainly, connections between a catheter and a pump through the use of a catheter port, such as shown in Duggan for example, are known. Therefore, the Office Action's suggestion that more is required in the drawings is inconsistent with the requirements of 37 C.F.R. 1.83(b).

Accordingly, withdrawal of this objection is respectfully requested.

Cancelled Claim

The features of claim 81 were incorporated into independent claim 80 and claim 81 has been cancelled, thus mooting the rejection of this claim.

Amendments to the Claims

Claims 80, 102 and 103 have been amended to clarify the intended scope of the claims. For example, claim 80 now recites "at least one of the openings capable of directing a catheter away from the central axis of the cannula." Claims 102 and 103 have been similarly amended. Support for this amendment is at least found in Figures 4-9a and 12a-12b, as well as the associated description accompanying those figures and the description found on page 19, lines 19-21 of the specification as filed which explains that the delivery elements may be catheters. In

addition, claims 80, 102 and 103 have been amended to clarify that they are directed toward an implantable system. Support for this is at least found in Figure 1 of the specification as filed as well as the associated description. Therefore, no new matter was added by these amendments.

Claim 85 has been amended to recite "wherein the therapy delivery device is coupled to a first and a second catheter, wherein the delivery system is configured to deliver at least two drugs through the first and second catheters." Support for this amendment is at least found on page 22, lines 1-3 of the specification as filed, as well as in the claims 1, 4, 20, 24-25 of the parent application as originally filed, provided below, thus no new matter has been added.

Claim 92 has been amended to avoid the suggestion that the claim is directed toward a system performing a process.

Claims 95 and 97 have been amended to correct a minor informality and no change in the scope of the claims was made or intended.

Claims 96 and 98 have been amended to more distinctly point out the claimed subject matter and to correct an incongruity noted by the Office Action. Applicants respectfully submit that the amended meaning was inherent in the claims; therefore no new matter was added.

Claim 105 has been amended to correspond to the amendments of claim 103 so as to avoid any suggestion that the programmer is implantable. No new matter was added by this clarifying amendment.

Objection to the Specification – Antecedent Basis

The Specification was objected to under MPEP 608.01(o) as failing to provide proper antecedent basis for how the use of the term "setting maximum value" as recited in claims 95-98. While this section of the MPEP does indicate that amendments to the specification as filed may be required if the specification as filed does not include a term used in a pending claim, Applicants point to the paper submitted on June 21, 2005 where Applications amended the specification as filed, on pg 19, as follows to provide proper antecedent basis for the terms as used in the claims:

> Referring back to Figure 11, the present invention may also be implemented within a drug delivery system. In this embodiment, the therapy delivery device is a pump 10A and the therapy delivery element is a catheter 23. A therapy deliver

> device or pump 10A made in accordance with the preferred embodiment may be implanted below the skin of a patient. The device has a port 27 into which a hypodermic needle can be inserted through the skin to inject a quantity of a liquid agent, such as a medication or drug. The liquid agent is delivered from the pump 10A through a catheter port 20A into a therapy delivery element or a catheter 23. Catheter 23 is positioned to deliver the agent to specific infusion sites in a brain (B). Pump 10A may take the form of the device numbered 10 that is shown in U.S. Patent No. 4,692,147 (Duggan), assigned to Medtronic, Inc., Minneapolis, Minnesota, which is incorporated by reference in its entirety. Settings of the pump 10A, such as frequency of delivery of medication and amount of medication to be delivered, can be adjusted to obtain the intended effect.

As noted in the prior response, Duggan, which was incorporated by reference, plainly discloses that parameters, such as frequency of delivery and amount of delivery, can be adjusted to provide the intended affect (*see* Duggan, C. 5, L. 63 – C. 6, L. 2) and therefore Duggan provides adequate support for such an amendment. Naturally, the term "parameter" is not identical to the term "setting," however, the MPEP 608.01(o) plainly states that "While an application is not limited to the nomenclature used in the application as filed, he or she should make appropriate amendments of the specification whenever this nomenclature is departed from by amendments of the claims so as to have clear support or antecedent basis in the specification for the new terms appearing in the claims." (Emphasis added). Therefore, the previous amendment to the specification plainly provides antecedent basis for the term setting. Given this prior amendment and the plain support for varying parameters provided by Duggan (*see* Duggan, C. 5, L. 63 – C. 6, L. 2), Applicants respectfully submit the specification and claims as currently pending do meet the requirements MPEP 608.01(o) with respect to the term "setting" to the extent that such an ordinary term required antecedent basis in the first place.

Accordingly, withdrawal of this objection is respectfully requested.

Rejection Under 35 U.S.C. § 112, ¶ 2

Claims 96 was rejected under 35 U.S.C. § 112, ¶ 2 as failing to particularly point out and claim the intended subject matter. Applicants note that claim 98 had a similar issue. In response, claims 96 and 98 have been amended so that they are consistent with the claims from which they depend.

Accordingly, withdrawal of this ground of rejection is respectfully requested.

Rejection Under 35 U.S.C. § 112, ¶ 1

The Office Action rejected claims 80-86, 89-102 and 104-105 under 35 U.S.C. § 112, ¶ 1 for failing to meet the written description requirement. In particular, the Office Action suggested that the claims contain subject matter with was not described in the specification in such as way as to reasonably convey that the inventors had possession of the invention at the time of filing.

In response, Applicants first note that this case is a continuation of the parent case, U.S. Patent No. 6,353,762. Looking at the claims originally filed in the parent case, the following claims were originally filed:

1. A system for providing treatment therapy to a volume of neural tissue comprising in combination:

(a) a cannula having a lumen distal end, the lumen distal end having at least one opening, each opening capable of directing a lead outwardly along a predetermined trajectory;

(b) at least two leads insertable within the cannula, each lead having a lead distal end;

(c) at least one therapy delivery element at the lead distal end of each lead; and

(d) a therapy delivery device coupled to each therapy delivery element and capable of selectively providing treatment therapy via at least one therapy delivery element,

whereby the therapy delivery elements are positionable in a non-linear configuration to affect a volume of neural tissue.

4. A system as claimed in claim 1, wherein the therapy delivery device is a pump and the therapy delivery element is a catheter.

20. A method of affecting a volume of neural tissue comprising the steps of:

(a) inserting at least a first, second, and third therapy delivery elements through a cannula and into neural tissue;

(b) positioning the first, second, and third therapy delivery elements near a predetermined portion of the neural tissue in a nonlinear configuration; and

(c) selectively providing treatment therapy to first, second, and third therapy delivery elements to affect a predetermined volume of neural tissue.

25. A method as claimed in claim 20, wherein the therapy delivery elements are catheters and the treatment therapy is drug infusion.

26. A method as claimed in claim 25, further comprising the step of:

(d) selectively adjusting the relative drug delivery through each catheter.

(U.S. Patent 6,353,762, claims as filed). The originally filed claims are part of the written description and therefore indicate what was in the possession of the inventors at the time of filing. Plainly the concept of having multiple catheters configured as claimed in claim 25 and 26, which modify claim 20, was in the possession of the inventors at the time of filing. Therefore, the figures and the specification as filed must be read as previously suggested by Applicants – the depictions showing leads are also representative of how catheters may be configured. Therefore, contrary to the suggestion in the Office Action, Applicants at the time of filing had in their possession the concept of a plurality of catheters being implanted in a manner similar to the leads and electrodes shown in the figures.

More particularly, regarding claims 80 and 103, the Office Actions suggested that the concept of an implantable therapy delivery device that stores liquid agent and is coupled to a first and second catheter as recited was new matter. However, Figures 3-10 of the specification as filed show embodiments of leads with electrodes on the end of the leads. Plainly, in view of the

specification, see pg. 5 and pg. 21-22 for example, and the claims as filed in the original parent application, the leads and electrodes may be replaced with catheters. Therefore, more than ample support exists for these concepts and they do not add new matter.

Regarding claim 85, the Office Action suggested that the concept of coupling to first and second catheters as recited was new matter. However, claim 85 has been amended to more closely track the language of the originally filed claims and therefore, while Applicants do not agree with the Office Action's position, this rejection is believed to have been obviated. Furthermore, ample support exists in the Figures 3-10 and the claims 1, 4, 20, 25 and 26, provided above, of the parent specification as filed.

Regarding claim 91, the Office Action has suggested that the feature "determining a desired rate of infusing the liquid agent through the first catheter and the second catheter" adds new matter. However, the specification as filed discloses adjusting parameters such as the rate of infusion. (*See* Duggan, C. 5, L. 63 – C. 6, L. 2). Furthermore, the specification as filed discloses that parameters may be adjusted by a processor response signals received from a sensor, see specification as filed, pg. 15-22. Therefore, a person of ordinary skill in the art would understand that the applicants had in their possession at the time of filing the concept of "determining a desired rate of infusing…," which could be done based on the signals received from the sensor. Indeed, given that claim 26 as original filed in the parent case recited "selectively adjusting the relative drug delivery through each catheter," it seems relatively plain that Applicants were in possession of this feature at the time of filing and therefore the specification as filed did reasonably convey to a person of ordinary skill that Applicants were in possession of the above features at the time of filing.

Regarding the claims 92-94, the Office Action suggested that the use of a timer and adjusted parameter to control liquid agent delivery adds new matter. The specification as filed, on pg. 18-19, explains that that:

> It is desirable to reduce parameter values to the minimum level needed to establish the appropriate level of neuronal activity in the target nucleus. Superimposed on the algorithm just described is an additional algorithm to readjust all the parameter levels downward as far as possible. In Figure 14, Steps 410 through 415 constitute the method to do this. When parameters are changed, a timer is reset in step 415. If there is no need to change any stimulus parameters

> before the timer has counted out, then it may be possible due to changes in neuronal activity to reduce the parameter values and still maintain appropriate levels of neuronal activity in the target neurons. At the end of the programmed time interval, device 14 tries reducing a parameter in step 413 to determine if control is maintained. If it is, the various parameter values will be ratcheted down until such time as the sensor values again indicate a need to increase them. When the algorithms in Figure 14 follow the order of parameter selection indicated, other sequences may be programmed by the clinician.

Therefore, the specification as filed plainly conveys to a person of ordinary skill in the art that Applicants were possession of the concept of using the timer. As the Applicant also explained that the invention could be implemented with a drug delivery system, where the leads are configured to delivery drugs, *see* specification as filed, pg. 21-22 (along with the above originally filed claims), and explained that parameters of the drug delivery may be adjusted, *see* Duggan, C. 5, L. 63 – C. 6, L. 2, the specification as filed does reasonably convey to a person of ordinary skill in the art that the Applicants were in possession of the invention as claimed in claims 92-94 at the time of filing.

Regarding claims 95-98, the Office Action suggests that increasing of the infusion rate while not exceeding a maximum value in response to excessive target activity is new matter. However, as noted above, the specification as filed, particularly Duggan, C. 5, L. 63 – C. 6, L. 2 does disclose adjusting parameters such as infusion rate. In addition, the specification as filed, on pg. 18 explains that:

> If, on the other hand, the stimulation electrode is placed in a location which the clinicians would like to activate in order to increase an inhibition of the target nucleus, the algorithm would follow a different sequence of events. In the preferred embodiment, the frequency parameter would be fixed at a value chosen by the clinician to facilitate neuronal activity in step 430 (Figure 17) through path 420A. In steps 431 and 432 he algorithm uses the values of the feedback sensor to determine if neuronal activity being adequately controlled. In this case, inadequate control indicates that the neuronal activity of the stimulation target is too low. Neuronal activity is increased by first increasing stimulation amplitude (step 434) provided it doesn't exceed the programmed maximum value checked for in step 433. When maximum amplitude is reached, the algorithm increases pulse width to its maximum value in steps 435 and 436 (Figure 18). A lack of adequate reduction of neuronal activity in the target nucleus, even though maximum parameters are used, is indicated to the clinician in step 437. After

> steps 434, 436 and 43, the algorithm returns to step 431 through path 431A, and the feedback sensor again is read.

Thus, the specification as filed plainly disclosed the features of adjusting parameters until the parameters reaches a maximum as recited in claims 95-98. While the above portion of the specification is discussing electrical stimulation, this is merely one embodiment and as previously noted, at the time of filing it was plainly contemplated that this embodiment could be modified by using catheters (see, for example, originally filed claims 1, 4, 20 and 25-26 as well as the specification as filed, pg. 5 and pg. 21-22). Applicants respectfully submit that the originally filed disclosure does convey to a person of ordinary skill in the art that Applicants where in possession of the subject matter of claims 95-98.

Regarding claim 99, the Office Action suggests that the concept of a second sensor is new matter. However, U.S. Patent No. 5,259,387 to dePinto (dePinto), which was incorporated by reference into the specification as filed on page 15, ln. 10-14, discloses a plurality of electrodes used to provide EEG signals. (dePinto, C. 2, L. 60 – C. 3, L. 2). Accordingly, the specification as filed does indicate that Applicants were in possession of the concept of using multiple sensors.

Regarding claim 102, The Office Action suggested that a pump coupled to two catheters as recited in claim 102 was not disclosed in the specification as filed. However, Applicants respectfully submit that a person of ordinary skill in the art would plainly appreciate from the originally filed claims 20, 25 and 26 that Applicants were in possession of such a pump storing drug and connected to first and second catheters as recited in claims 102. In addition, U.S. Patent No. 5,711,316 to Elsberry, which was incorporated by reference in the present application on page 14 of the specification as filed, provides additional support for these features. (See Elsberry, C. 3, L. 39-50).

Regarding claim 104, the Office Action suggested that a sensor in proximity to the liquid delivery position as recited in claim 104 was not disclosed in the specification as filed. In response, Applicants first note that the specification as filed discloses that the implanted electrodes may act as sensors (specification as filed, pg. 15, L. 7-9). The specification as filed further explains that lead members may contain more than one electrode near the distal end.

Thus, the specification as filed discloses that a stimulus delivery position can be positioned near a target set of neurons and further discloses that a sensor can be in the same position as the stimulus delivery position or can be near the stimulus delivery position (in the case of a lead with multiple electrodes). The specification as filed further discloses that leads may be used to delivery electrical stimulation (have electrodes) and also delivery drugs (see specification as filed, pg. 21, L. 21 – pg. 22, L. 3). Furthermore, Figure 23 of the specification as filed illustrates an embodiment of a lead with multiple delivery elements on a lead near the distal end. And as is known, catheters deliver fluids to an opening in the end of the catheter. According, a person of ordinary skill in the art would appreciate from the disclosure provided in the specification as filed that did disclose having a sensor in proximity to a therapy delivery element, which may be a catheter.

Accordingly, for at least the above reasons, withdrawal of this ground of rejection is respectfully requested.

Rejection Under 35 U.S.C §102(e) - Gillis

Claims 80-83, 85-86, 89, 103 and 107 were rejected under 35 U.S.C. § 102(e) as anticipated by Gillis. While not addressing the issue of whether Gillis can be properly considered prior art for the present pending application (but reserving the right to do so), the rejection is respectfully traversed below.

The Office Action, on page 9, suggested that "[o]utwardly could be along the central axis if away from the device." For the purpose of this response, this construction will be assumed to be proper. Accordingly, claim 80 has been amended to recite "at least one of the openings capable of directing a catheter away from the central axis of the cannula." Plainly, as noted in the prior office action, Gillis fails to disclose such a feature when outwardly is construed to be away from a central axis of the cannula. Thus, for at least the above reasons Gillis fails to disclose all the limitations of claim 80. As Gillis does not disclose all the limitations of claim 80, Gillis cannot be said to anticipate claim 80.

Claims 82-83, 85-86 and 89 depend from claim 80 and necessarily include at least one limitation not disclosed by Gillis, therefore Gillis cannot fairly be said to anticipate claims 82-83, 85-86 and 89.

Independent claim 103 recites a feature similar to the above discussed feature of claim 80, therefore, Gillis cannot be said to anticipate claim 103 for at least the above discussed reason that Gillis does not anticipate claim 80.

Claim 107 depend from claim 103 and necessarily include at least one limitation not disclosed by Gillis, therefore Gillis cannot fairly be said to anticipate claim 107.

Accordingly, withdrawal of this ground of rejection is respectfully requested.

Rejection Under 35 U.S.C. § 103(a) – Howard & Elsberry

Claims 80-83, 85, 86, 89, 90, 103, 106 and 107 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Howard in view of McGuckin. The Office Action rejected claims 84 and 102 under 35 U.S.C. § 103(a) as being unpatentable over Howard in view of McGuckin in further view Elsberry. The Office Action rejected claims 91-92, 95-101 and 104-105 under 35 U.S.C. § 103(a) as being unpatentable over Howard in view of McGuckin in further view of Cosgrove. The Office Action rejected claim 94 under 35 U.S.C. § 103(a) as being unpatentable over Howard in view of McGuckin and Cosgrove and in further view of Abbott. Thus, the pending claims stand rejected under the combination of Howard and McGuckin, by themselves or in combination with additional references.

Claims 80, 102 and 103 have been amended to clarify that they are directed toward implantable systems. Neither Howard nor McGuckin discloses such a configuration. Nor, for example, would the metal leads used by McGuckin be suitable for extending from implanted delivery position in a patient's brain, along a person's neck to an implanted pump located in a person's torso. Therefore, one would not be expected to combine the teaching of McGuckin with any of the references of record to form something similar to what the present application discloses with any expectation of success. Accordingly, the combination of Howard and McGuckin, alone or in combination with the other references of record, cannot be said to disclose, suggest or teach all the features of the pending independent claims 80, 102 or 103. Therefore, the references of record fail to support a *prima facie* case of obviousness with respect to claims 80, 102 and 103 and these claims are therefore nonobvious in view of the references of record.

The remaining pending claims depend from one of the above independent claims and are nonobvious for at least the above reasons and for the additional limitations recited therein.

Accordingly, withdrawal of this ground of rejection is respectfully requested.

Nonstatutory Double Patenting Rejection

Claims 80-83, 85-86, 89, 103 and 107 were rejected under nonstatutory nonobvious type double patenting. While not agreeing with the comments provided in the Office Action, to advance prosecution Applicants submit a terminal disclaimer obviating this rejection.

CONCLUSION

All rejections having been addressed, the Applicant respectfully submits that the instant application is in condition for allowance, and earnestly solicits prompt notification of the same.

Respectfully submitted,

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